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| 10/568,830 | 11/06/2006 | Franz-Wilhelm Koerd | P71027US0 | 9545 |

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| EXAMINER |
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SAINT SURIN, JACQUES M

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| ART UNIT | PAPER NUMBER |
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2856

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11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,830

Applicant(s)

KOERDT ET AL.

Examiner

J M. SAINT SURIN

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/22/06, 11/06/06 and 01/16/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date 01/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The preliminary amendment of 02/22/06 is acknowledged, considered and entered.

Drawings

2. The drawings filed on 02/22/06 are accepted by the examiner.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

4. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Baumgartner (US Patent 5,123,286).

Regarding claim 1, Baumgartner discloses a method of measuring a signal transit time (col. 1, lines 8-13) in a medical liquid (medium 6 is a liquid or fluid, col. 4, lines 29-35 recites calculating rate of flow in any medium) required by a signal to pass

through a measurement zone (1) from an ultrasonic transmitter (2) to an ultrasonic receiver (3) (col. 5, lines , wherein a line carrying the medical liquid (6) is arranged in the measurement zone (1), or for measuring changes in the signal transit time (col. 3, lines 23-27) whereby the ultrasonic transmitter (2) emits a step-like signal (see Figs 2 and 3) and the step-like signal passes through the measurement zone (1), resulting in an oscillation-like received signal (5), oscillating about a resting level (col. 3, lines 51-52) on the ultrasonic receiver (3), the received signal being sampled at regular intervals .DELTA.t and detected, the oscillator-like received signal is checked on the basis of a selection criterion at least during a half-period to determine whether it is the received signal produced by the step-like signal, and when the result of this check is positive, the signal transit time or the change in the signal transit time is determined with the help of an interpolated or extrapolated contact point of the oscillator-like received signal with the resting level in a received signal-time diagram (see col. 5, lines 1-38).

Regarding claim 2, Baumgartner discloses the point used as the interpolated or extrapolated contact point is the point in the received signal-time diagram at which the oscillator-like received signal at the beginning of the first half-period differs from the resting level, and the signal transit time is derived from the signal transit time thus determined (col. 5, lines 55 to col. 6, line 2 and col. 6, lines 52-61).

Regarding claims 4-7, Baumgartner discloses the two end walls 2 and 3 of the ultrasonic measuring tube 1, which are made of high-grade steel, are transparent to ultrasonic waves only if their thickness is an integral multiple of one-half the ultrasonic

wavelength in steel. However, even when this sizing rule is observed, the received signal S.sub.2 will deviate from the shape of the nearly rectangular transmitted pulse S.sub.1 in that it no longer has any steep edges but consists of a group of waves that increases in amplitude over several cycles and then decays (col. 3, lines 13-22).

Baumgartner further discloses an instantaneous value of the threshold voltage (V) is compared with an amplitude of each positive half-wave of the received signal (S.sub.2) and that instantaneous value of the threshold voltage is stored in a group of threshold voltage values corresponding to a particular positive half-wave if the particular positive half-wave exceeds the threshold voltage value. Next, propagation delays (T.sub.A, T.sub.B, T.sub.C, T.sub.D) for each positive half-wave, wherein each of said plurality of propagation delays are determined by defining the propagation delay for each positive half-wave to be a zero-crossing point following a point at which the amplitude of the positive half-wave falls below the instantaneous threshold voltage (V) (col. 2, lines 7-20).

Regarding claims 8-12, Baumgartner discloses the method according to claim 1, characterized in that the extreme value (18) of the oscillator-like received signal (12) is determined during the half-period (14) and is compared with a reference value and the subsequent half-period (15) is sampled and detected and the extreme value (19) of the oscillator-like received signal (12) is determined during the subsequent half-period (15) and compared with a reference value and the duration of one or more half-periods (14, 15) of the oscillator-like received signal (12) is determined as the selection criterion and is compared with a reference value (col. 3, lines 45 to col. 4, line 1).

Regarding claim 14, it is rejected for the reasons set forth for claim 1 as being a device to perform the functions of the method of claim 1 (see claim 3, col. 4, lines 9-61).

Regarding claim 15, Baumgartner discloses an electronic sequence-control and time-measurement module 16 comprises a microcomputer which coordinates the measuring process and effects the time measurement on the basis of the pulses delivered by the comparator switching circuit 14 and of the threshold voltages V.sub.A to V.sub.D assigned to them (col. 4, lines 66 to col. 5, line 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (US Patent 5,123,286) in view of Jahn et al. (US Patent 6,542,761).

Regarding claims 13 and 16, Baumgartner does not disclose the medical liquid is blood, dialysis liquid or an infusion liquid. Jahn discloses air detection as well as pressure monitoring in the arterial and venous blood treated in an extracorporeal cycle during dialysis treatment (col. 1, lines 5-8). It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize in Baumgartner the medical fluid of Jahn because it includes blood flow which analysis in the dialysis machine, provides reliable information for determining or evaluating parameters during medical procedures thereby, making the above combination more effective.

Regarding claim 17, although Baumgartner discloses receiver 3, it does not particularly disclose or suggest a blood volume sensor and an air detection sensor. Jahn discloses the ultrasonic measurement method can be carried out using opposite ultrasonic sensors (col. 3, lines 23-26). It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize in Baumgartner the blood volume sensor of Jahn because it would determine the relative blood volume of the fluid in the measurement chamber in a reliable manner.

Regarding claim 18, Baumgartner does not disclose an air detection sensor. Jahn discloses a system for air detection as well as pressure monitoring in the arterial and venous blood treated in an extracorporeal cycle during dialysis treatment (col. 1, lines 5-8). It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize in Baumgartner the air detection sensor of Jahn because by

using opposing ultrasonic sensors detection of air bubbles in the fluid specimen being measured would be accurately obtained in a reliable manner.

Regarding claim 3, Baumgartner discloses the point in the received signal-time diagram at which the oscillator-like received signal intersects the resting level after the first half-period is determined as the interpolated or extrapolated contact point, and the change in signal transit time is derived from the time thus determined (col. 5, line 60 to col. 6, line 2 and col. 6, lines 57-61).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J M. SAINT SURIN whose telephone number is (571)272-2206. The examiner can normally be reached on Mondays to Fridays between 9:30 A.M and 6:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron L. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacques M SAINT SURIN/
Examiner, Art Unit 2856